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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, Plaintiff, v. $38,406,717.42 IN UNITED STATES CURRENCY, Defendant-in-rem.	**VERIFIED COMPLAINT FOR FORFEITURE** 20 Civ. 6173

The United States, by its attorney, Audrey Strauss, Acting United States Attorney for the Southern District of New York, alleges for its complaint as follows:

I. JURISDICTION AND VENUE

1. This action is brought pursuant to Title 18, United States Code, Section 981 by the United States of America seeking the forfeiture of $38,406,717.42 in United States currency (the "Defendant Funds" or the "defendant-in-rem").

2. This Court has jurisdiction pursuant to Title 28, United States Code, Section 1355.

3. Venue is proper under Title 28, United States Code, Section 1355(b)(l)(A)

because certain actions and omissions giving rise to forfeiture took place in the Southern District of New York and pursuant to Title 28, United States Code, Section 1395 because the defendant-in-rem has been transferred to the Southern District of New York.

4. The Defendant Funds constitute property constituting and derived from proceeds of violations of the federal Anti-Kickback Statute in violation of Title 41, United States Code, Sections 1320a–7b, and property traceable to such property; and are thus subject to forfeiture to the United States pursuant to Title 18, United States Code, Section 981(a)(l)(C).

II. FACTUAL ALLEGATIONS

5. From at least 2002 until in or around 2011, Novartis Pharmaceuticals Corporation ("Novartis"), acting through certain employees, violated the Anti-Kickback Statute, 42 U.S.C. §1320a-7b(b). On or about June 29, 2020, Novartis and the United States entered into a Stipulation and Order of Settlement and Dismissal (the "Stipulation") in *United States, et al. ex rel. Bilotta* v. *Novartis Pharmaceuticals Corp.*, No. 11 Civ. 071 (PGG), wherein, *inter alia*, Novartis admitted a set of facts set forth in paragraph 2 of the Stipulation (the "Admissions") and agreed to forfeit $38,406,717.42, (the "Defendant Funds"), to the United States. The Defendant Funds represent proceeds of Novartis's violations of the AKS. The Stipulation was so ordered by the Court on July 1, 2020, and is attached hereto as Exhibit A.

6. As described more fully in the Admissions, and among other conduct in violation of the Anti-Kickback Statute: (1) from January 2002 to November 2011, Novartis offered and paid remuneration in the form of meals and honoraria payments to health care practitioners ("HCPs") who spoke at or attended Novartis events to induce them to prescribe Lotrel, Valturna, Starlix, Tekamlo, Diovan HCT, Tekturna HCT, and Exforge HCT; and (2) from January 2010 to November 2011, Novartis offered and paid remuneration in the form of meals

and honoraria payments to HCPs who spoke at or attended Novartis events to induce them to prescribe Diovan, Tekturna, and Exforge (collectively with Lotrel, Valturna, Starlix, Tekamlo, Diovan HCT, Tekturna HCT, and Exforge HCT, the "Covered Drugs"). The Covered Drugs were all manufactured and sold by Novartis. Novartis was aware that the HCPs who received remuneration from Novartis also prescribed the Covered Drugs to individuals who received health insurance coverage through Medicare, Medicaid and/or TRICARE (the "Federal Health Care Programs") and thereby caused the Federal Health Care Programs to pay millions of dollars for the Covered Drugs. Novartis obtained at least $38,406,717.42 in proceeds as a result of this conduct.

III. THE DEFENDANT IN REM

7. As part of Novartis' obligations under the Stipulation, on or about July 21, 2020, Novartis transferred the Defendant Funds to the United States Marshals Service in the Southern District of New York as a substitute *res* for proceeds of its conduct as set forth above. Novartis agrees that the Defendant Funds are subject to forfeiture pursuant to United States Code, Section 981(a)(1)(C).

IV. CLAIM FOR FORFEITURE

8. Incorporated herein are the allegations contained in paragraphs one through seven of this Complaint.

9. Title 18, United States Code, Section 981(a)(l)(C) subjects to forfeiture "[a]ny property, real or personal, which constitutes or is derived from proceeds traceable to ... any offense constituting 'specified unlawful activity' (as defined in section 1956(c)(7) of this title), or a conspiracy to commit such offense."

10. "Specified unlawful activity" is defined in Title 18, United States Code, Section 1956(c)(7), and the term includes, among other things, a "any act or activity constituting an

offense involving a Federal health care offense," *id*. § 1956(c)(7)(F). Pursuant to Title 18, United States Code, Section 24, "the term 'Federal health care offense' means a violation of, or a criminal conspiracy to violate" a number of provisions, including the Anti-Kickback Statute, 42 U.S.C. 1320a–7b.

11. The Anti-Kickback Statute provides, in part, that:

> Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—
>
> (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
>
> (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
>
> shall be guilty of a felony[.]

42 U.S.C. 1320a–7b(b)(2).

12. By reason of the foregoing, the Defendant Funds are subject to forfeiture to the United States of America pursuant to Title 18, United States Code, Section 981(a)(l)(C) because the Defendant Funds constitute property derived from violations of the Anti-Kickback Statute.

WHEREFORE, plaintiff United States of America prays that process issue to enforce the forfeiture of the defendant-in-rem and that all persons having an interest in the defendant-in-rem be cited to appear and show cause why the forfeiture should not be decreed, and that this Court decree forfeiture of the defendant-in-rem to the United States of America for

disposition according to law, and that this Court grant plaintiff such further relief as this Court may deem just and proper, together with the costs and disbursements of this action.

Dated: New York, New York
August 6, 2020

AUDREY STRAUSS
Acting United States Attorney for the
Southern District of New York

By: */s/ Jacob M. Bergman*

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VERIFICATION

STATE OF NEW YORK)
COUNTY OF NEW YORK :
SOUTHERN DISTRICT OF NEW YORK)

JAN KUM, pursuant to Title 28, United States Code, Section 1746, hereby declares under penalty of perjury that she is a Special Agent with the Federal Bureau of Investigations; that she has read the foregoing Complaint and knows the contents thereof; that the same is true to the best of her knowledge, information and belief; and that the sources of her information and the grounds of her belief are her personal involvement in the investigation, and conversations with and documents prepared by law enforcement officers and others.

Executed on: August 4, 2020

JAN KUM
Special Agent
Federal Bureau of Investigation

EXHIBIT A

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, Plaintiff-Intervenor, v. NOVARTIS PHARMACEUTICALS CORP., Defendant.	:	11 Civ. 0071 (PGG) **STIPULATION AND ORDER OF SETTLEMENT AND DISMISSAL**

WHEREAS, this Stipulation and Order of Settlement and Dismissal (the "Stipulation") is entered into by and among (i) plaintiff the United States of America (the "United States" or the "Government"), by its attorney Audrey Strauss, Acting United States Attorney for the Southern District of New York; (ii) the *qui tam* relator Oswald Bilotta ("Relator"); and (iii) defendant Novartis Pharmaceuticals Corporation ("Novartis," and together with the United States and Relator, the "Settling Parties"), through their respective authorized representatives;

WHEREAS, in January 2011, Relator filed a complaint in the above-captioned action in the United States District Court for the Southern District of New York (the "Court") under the *qui tam* provisions of the False Claims Act, as amended, 31 U.S.C. § 3729 et seq. (the "FCA"), which complaint was subsequently amended on October 19, 2012, as of right on April 3, 2013 (pursuant to an unopposed motion dated March 21, 2013), and on July 10, 2013 (pursuant to a stipulation dated July 8, 2013), alleging, *inter alia*, that Novartis violated the FCA and the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) (the "AKS"), by, *inter alia*, paying doctors remuneration to prescribe the drugs Lotrel, Valturna, Starlix, Tekturna, Tekturna HCT, Diovan, Diovan HCT, Exforge and Exforge HCT through the mechanism of speaker program honoraria and related misconduct (the "Relator Action");

WHEREAS, on April 26, 2013, the United States intervened in the Relator Action against Novartis by filing a Notice of Election to Intervene and Complaint-in-Intervention in the above-referenced *qui tam* action, in which it is asserting claims against Novartis under the FCA and common law;

WHEREAS, on August 26, 2013, the United States filed an Amended Complaint-in-Intervention in this action (the "Government Complaint");

WHEREAS, on August 26, 2013, the State of New York also intervened in this action;

WHEREAS, the United States alleges that (i) from January 1, 2002, through November 21, 2011, Novartis offered and paid remuneration in the form of cash, meals, alcohol, hotels, travel, entertainment, and honoraria payments to health care practitioners ("HCPs") who spoke at or attended Novartis speaker events, roundtables, speaker training meetings or lunch-n-learns to induce them to prescribe Lotrel, Valturna, Starlix, Tekamlo, Diovan HCT, Tekturna HCT, and Exforge HCT, in violation of the AKS, and thereby caused false claims for prescriptions for those drugs to be submitted to and paid by Medicare, Medicaid, the Department of Veterans Affairs and TRICARE, in violation of the FCA; and (ii) from January 1, 2010, through November 21, 2011, Novartis paid remuneration in the form of cash, meals, alcohol, hotels, travel, entertainment, and honoraria payments to HCPs who spoke at or attended Novartis speaker events, roundtables, speaker training meetings or lunch-n-learns to induce them to prescribe Diovan, Tekturna, and Exforge in violation of the AKS, and thereby caused false claims for prescriptions for Diovan, Tekturna, and Exforge to be submitted to and paid by Medicare, Medicaid, the Department of Veterans Affairs and TRICARE, in violation of the FCA. The conduct described in this Paragraph is the "Covered Conduct" for purposes of this Stipulation;

WHEREAS, Novartis intends to enter into separate settlement agreements with various States (the "State Settlements") to resolve claims under state law for the Covered Conduct, and has agreed to pay a total of $48,151,273.66 to the States pursuant to the State Settlements;

WHEREAS, the Settling Parties have, through this Stipulation, reached a full and final mutually agreeable resolution addressing the claims asserted against Novartis in the Government Complaint and the Relator Action, for the Covered Conduct;

WHEREAS, the Relator's claim to a share of the proceeds from the settlement of claims arising from the Relator Action will be the subject of a separate agreement between Relator and the United States;

NOW, THEREFORE, upon the Settling Parties' agreement, it is hereby ORDERED that:

1. The Settling Parties agree that this Court has subject matter jurisdiction over this action and consent to this Court's exercise of personal jurisdiction over each of them.

2. Novartis admits, acknowledges, and accepts responsibility for the following facts and conduct:

The Anti-Kickback Statute

a. The AKS prohibits pharmaceutical companies, such as Novartis, from knowingly and willfully providing remuneration to doctors in order to induce them to write prescriptions for the company's pharmaceutical products that are ultimately paid for by federal health care programs.

b. Between January 2002 and November 2011 (the "Relevant Period"), Novartis understood that it had to comply with the AKS. Throughout the Relevant Period, Novartis had an ethics and compliance policy that applied to all of its employees and associates, which stated that the AKS "makes it a criminal offense to, among other things, knowingly and willfully offer . . . any 'remuneration' in exchange for, or to induce the . . . recommendation of, any item or service for which payment may be made under Medicare [or] Medicaid."

c. During the Relevant Period, Novartis knew that Medicare providers, Part D plan sponsors and pharmacies that contracted with Part D plan sponsors were required to agree that they would comply with applicable laws and

regulations, including, but not limited to, the Anti-Kickback Statute and the False Claims Act.

d. During the Relevant Period, Novartis knew that state Medicaid programs required providers, including doctors and pharmacies, to certify compliance with federal requirements and such certification encompassed compliance with the Anti-Kickback Statute.

e. Moreover, during the Relevant Period, Novartis knew that the TRICARE program required providers to agree to abide by federal laws and regulations. Similarly, pharmacies filling prescriptions for TRICARE beneficiaries were also required to abide by federal laws.

Marketing of the Covered Drugs through Meetings and Events

f. During the Relevant Period, Novartis marketed and sold a number of drugs to treat hypertension, including Lotrel, Diovan and Diovan HCT, Exforge and Exforge HCT, Tekturna and Tekturna HCT, Valturna, and Tekamlo. Novartis also marketed and sold Starlix, a drug to treat Type 2 diabetes (collectively, the "Covered Drugs").

g. Lotrel was approved by the FDA in 1995, Diovan in 1996, and Diovan HCT in 1998. Starlix was approved in 2000. Exforge and Exforge HCT were approved by the FDA in 2007 and 2009, respectively. Exforge is a combination of Diovan and amlodipine besylate, which was approved by the FDA for treatment of hypertension in 1992. Exforge HCT combines Exforge with a diuretic, hydrochlorothiazide. Tekturna and Tekturna HCT were approved by the FDA in 2007 and 2008, respectively. The FDA approved Valturna in 2009 and Tekamlo in 2010.

h. Novartis conducted meetings and events as part of its marketing efforts for each of the Covered Drugs, including events referred to as speaker programs and roundtables.

i. Pursuant to the Novartis compliance policies in place during the Relevant Period, speaker programs were supposed to be promotional programs led by a speaker who was approved and trained by the company and who received an honorarium for presenting an on-label and medically relevant slide presentation and Q&A session related to a Novartis product. Novartis paid for the attendees' meals and alcohol for programs held in restaurants.

j. Pursuant to the Novartis compliance policies in place during part of the Relevant Period, roundtables were supposed to be events, typically held at restaurants, where a Novartis sales representative used company-approved promotional materials to facilitate a medical discussion between the doctors in attendance concerning one or more Novartis drugs. Novartis

paid for the attendees' meals and alcohol. Novartis's policies allowed roundtables to include dinners attended by a single doctor hosted by a sales representative.

k. In 2002, Novartis signed the PhRMA Code, an industry-wide code of conduct, and adopted internal compliance policies in response to the Code. The Code stated that meals should only be provided to doctors in connection with "[i]nformational presentations and discussions" that "provide scientific or educational value", and that were "modest," "occur[red] in a venue and manner conducive to informational communication," and were provided "on [no] more than an occasional basis."

l. The majority of Novartis's speaker programs and roundtables were organized by sales representatives, who selected the venue, chose the speakers, and determined which doctors to invite.

Budgets for Promotional Programs

m. Novartis sales representatives were provided with budgets specifically for promotional programs, which included speaker programs and roundtables.

n. Many Novartis sales managers directed their sales representatives to spend all of their budgets for promotional programs.

o. Many Novartis sales representatives were specifically evaluated in their annual reviews as to how much of their budget for promotional programs they had used, as part of an evaluation of their overall sales efforts. If a sales representative failed to spend all of their budget, that could be a negative factor in their annual review.

p. Novartis incentivized its sales representatives and managers through bonus compensation to grow the local market share of the Novartis drugs for which they were responsible.

q. "Share of voice" is a marketing concept that measures a pharmaceutical company's marketing presence relative to competitors. A company's "share of voice" for a drug is equal to doctors' exposure to marketing for that drug, divided by their exposure to marketing for all drugs in that class. This exposure can include attendance at events like speaker programs and roundtables.

r. A presentation Novartis marketing executives sent to Novartis's Chief Operating Officer in 2005 stated that Novartis aimed to "[e]stablish Novartis CV [cardiovascular] franchise as the 800-pound gorilla" in that space by increasing its annual spending on "meetings and events" like speaker programs and roundtables from $57 million to $105 million.

s. As a result of the Covered Conduct, and the conduct to which Novartis admitted and accepted responsibility for in this Paragraph 2, Novartis obtained at least $40 million in net proceeds from prescriptions of the Covered Drugs that were ultimately reimbursed by Federal health care programs.

Selection of Speakers

t. Throughout the Relevant Period, Novartis representatives and their managers had broad discretion to decide which local doctors to nominate to become company-approved speakers.

u. Novartis gave its sales representatives prescribing data that showed the number of prescriptions for Novartis and competitor drugs written by the doctors in their territories. The Novartis sales force used this prescribing data to identify high-volume prescribers and track their prescriptions over time.

v. Using this prescribing data, some Novartis sales representatives selected high-prescribing doctors to become speakers and intended the honoraria paid to induce these doctors to continue to write or write more Novartis products.

w. During the Relevant Period, Novartis paid many high-prescribing doctors tens or hundreds of thousands of dollars in honoraria. For instance, over the course of the Relevant Period, Novartis paid over $320,000 in honorarium to a doctor who wrote more than 8,000 prescriptions for the Covered Drugs; over $220,000 in honorarium for a doctor who wrote more than 9,000 prescriptions for the Covered Drugs; and over $200,000 to a doctor who wrote more than 3,600 prescriptions for the Covered Drugs.

Excessive Meal and Alcohol Spend

x. Some Novartis sales representatives hosted speaker programs or roundtables at expensive restaurants, intending to induce the doctors in attendance to continue to write or write more Novartis prescriptions.

y. During the Relevant Period, Novartis sales representatives conducted speaker programs and roundtables at some of the most expensive restaurants in the United States, including Masa, Daniel, Gramercy Tavern, Il Mulino, Babbo, Peter Luger, Le Bernardin, and Eleven Madison Park in New York City; Charlie Palmer's in Washington, D.C.; Morton's Steakhouse and the Four Seasons in Chicago, Illinois; Joe's Stone Crab in Miami; Abacus, Nobu and the Four Seasons in Dallas; Gary Danko in San Francisco; Patina and Matsuhisa in Los Angeles; Grill 225 in South Carolina; and Commander's Palace in New Orleans.

z. Throughout the Relevant Period, according to Novartis database information about its programs, more than 12,000 speaker programs and roundtables had meal spends that were considerably in excess of the $125 per person limit set by Novartis's compliance policies. For example, in 2008, at a speaker program held at Ruth's Chris Steakhouse in Pikesville, Maryland, Novartis held an event with only one doctor in the audience for the speaker's presentation, at which it spent $448 per person on food and alcohol, in addition to the $1,000 honorarium payment provided to the speaker. In other examples, in 2008, Novartis spent $521 per person for food and alcohol at a dinner held at Skye Restaurant in Peoria, Arizona, and $680 per person for a dinner event held at Danton's Gulf Coast Seafood Restaurant in Houston, Texas.

aa. In 2006, an internal Novartis presentation noted that between August 2005 and April 2006 "[o]ver 24% of the [speaker] events appear to have exceeded the guideline for average [food and beverage] cost per attendee in major cities." It noted that one of the "[r]easons for excessive costs per person" was that "[e]vents are planned with high costs (e.g. very exclusive places, expensive menu choices, no control over alcohol spending)."

bb. In certain instances, Novartis's internal records understated how much was spent per doctor at each event, as some Novartis employees falsified records to make it appear that the amount spent on alcohol and food for doctors at speaker programs and roundtables was less than what was actually spent.

cc. During the Relevant Period, Novartis typically paid for alcohol provided at Novartis's speaker programs and roundtables. Some doctors demanded expensive bottles of wine. Doctors sometimes consumed alcohol in large quantities at these events, to the point of intoxication.

dd. During the Relevant Period, some Novartis sales representatives conducted speaker programs and roundtables on the Covered Drugs at venues where the focus was on entertainment, including fishing trips, sporting events, wine tastings, and hibachi tables. Novartis conducted hundreds of events at wineries and golf clubs. Sales representatives also conducted roundtables at Hooters.

Minimal Medical Discussion

ee. Although Novartis's ethics and compliance policies required that speaker programs and roundtables provide medical information regarding the company's products to health care practitioners, at many Novartis events, there was little to no medical discussion.

ff. At many of the speaker programs, the sales representative hosting the event did not require the speaker, who was being paid an honorarium, to

deliver a presentation at all, or allowed the speaker to click through the power point presentation in a matter of minutes. In those instances, the majority of the time was spent socializing and enjoying dinner.

gg. Novartis in a number of instances paid doctors honoraria for purportedly speaking at events that never took place.

hh. On Long Island, at least one sales representative organized fraudulent speaker programs by arranging for a restaurant to create fake receipts to make it appear that a dinner had taken place, and then using the budgeted funds to purchase gift cards that were distributed to high-prescribing doctors. Doctors were then also paid honoraria for "speaking" at these sham events.

Repeat Attendance

ii. Novartis had staff in its marketing science group to measure its return on investment ("ROI") from speaker programs and roundtables, based on the number of new prescriptions for its drugs written by doctors in attendance.

jj. In July 2004, Novartis's marketing science group sought to determine whether its meetings and events, including a doctor's repeated attendance at events, had any "impact on share growth."

kk. The following month, Novartis's marketing science group presented an analysis showing that, for Lotrel roundtables, the ROI for doctors who attended more than one roundtable was 1,200%.

ll. In 2005, in response to the direction to double Novartis's "share of voice" in cardiovascular meetings and events, Novartis executives developed "goals" for the number of speaker programs and roundtables Novartis sales representatives should hold each month.

mm. In November 2005, a Novartis sales executive wrote an email in which she stated that certain proposed "goals" for the number of speaker programs and roundtables to be expected of Novartis sales representatives for the months of January and February 2006 were "very difficult to defend [as] . . . achievable," and further that "attendance by these [doctors] would need to be excessive." Novartis ultimately set expectations "on the higher end" of what she thought was "possible."

nn. In 2007, the marketing science group recommended that high-prescribers of hypertensive drugs attend approximately a dozen meetings and events on Diovan, Diovan HCT, and Lotrel each year. The group reaffirmed these recommendations in 2008. These recommendations informed the national budgets Novartis set for its meetings and events.

oo. To achieve these goals, many Novartis representatives would repeatedly invite the same doctors to attend promotional programs for the same drugs and presentations with the same title. Novartis's records show that more than 19,235 doctors attended programs with the exact same title three or more times in a six-month period.

pp. In thousands of instances, Novartis paid for the same group of doctors, often colleagues or friends, to have dinners together repeatedly (along with other doctors or health care providers on occasion). Doctors in these groups would sometimes rotate being the speaker and receiving the honorarium payment.

qq. For example, five doctors in Harrisburg Pennsylvania went to more than 100 speaker program events at which some or all of the five doctors were in attendance over the course of five years, sometimes as often as five times a month. At these events, one of the five doctors would take turns being the designated speaker and receiving the honorarium payment.

rr. In Rockford Illinois, Novartis held 124 speaker programs over the course of eight years at which the same ten doctors or a subset of that group of doctors were the only persons in attendance. The same doctor was paid by Novartis to speak at 102 of those events. Some of the doctors who attended received a portion of that speaker's honoraria payment as a cash payment.

Novartis's Compliance Program

ss. Despite the known AKS risk posed by conducting meetings and events, during the Relevant Period, Novartis failed to develop and implement a compliance program that adequately ensured that its sales personnel was not using Novartis speaker and roundtable events as a means to induce doctors to prescribe Novartis drugs in violation of the AKS.

tt. Novartis created a compliance department in 1999, but did not allocate the personnel and resources to adequately monitor that the tens of thousands of speaker and roundtable events that Novartis organized throughout the country each year complied with the AKS.

uu. For the first two years of its existence, from 1999-2001, Novartis's compliance department consisted of one employee.

vv. While Novartis hired additional compliance personnel in later years, it did not employ sufficient staff to investigate potential AKS violations. As a result, there was a large backlog of potential AKS violations that needed to be investigated. Because of this backlog and the resulting passage of time, in many cases Novartis did not investigate potential misconduct at all.

ww. Novartis did not conduct a comprehensive field audit of speaker events until 2008, after approximately 90 percent of the events at issue in this case had already occurred. Novartis supervisors and compliance staff attended only a small number of the hundreds of thousands of speaker and roundtable events that Novartis arranged during the Relevant Period. Prior to the 2008 audit, sales representatives would typically receive advance notice if their programs were going to be audited.

xx. Even though Novartis adopted a policy in 2002 prohibiting a doctor from bringing a spouse or guest who was not a prescribing health care professional to promotional programs, in practice spouses or other guests were often invited to or allowed to attend such dinners.

yy. During part of the Relevant Period, Novartis compliance policies allowed sales representatives to spend as much as $125 on each doctor's meal and alcohol, regardless of where in the United States the dinner event was located. Novartis policies also set no limits on how many dinner events doctors could attend concerning the same drug.

zz. Novartis's compliance training materials suggested that emails advocating illegal kickbacks were improper in part because they "reflect[] ignorance of the import of written communications, and put[] the Company at risk." Novartis's Chief Compliance Officer also stated in training presentations: "If you don't have to write it, don't. Consider using the phone."

The 2010 Settlement and Corporate Integrity Agreement

aaa. In 2010, Novartis settled with the United States claims relating to Diovan, Exforge, Tekturna, Trileptal, Zelnorm, and Sandostatin. In that suit, the United States alleged that, between 2002 and 2009, Novartis provided illegal remuneration to doctors, through mechanisms such as speaker programs, advisory boards, and gifts (including entertainment, travel, and meals), to induce them to prescribe these drugs, in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b).

bbb. As part of that settlement, in September 2010 Novartis entered into a five-year Corporate Integrity Agreement ("2010 CIA") with the United States Department of Health and Human Services Office of Inspector General. The 2010 CIA required Novartis to make various changes to its auditing, monitoring, investigations, discipline, and other compliance policies.

ccc. The 2010 CIA also required an outside expert to audit Novartis's compliance program.

ddd. The 2010 CIA required the expert to conduct a "Year One Compliance Program Effectiveness Review" a year after the 2010 CIA went into

> effect. As part of the review, the expert concluded that Novartis had only "partially" met its compliance goals in certain areas. For example, the expert concluded that compliance monitoring had still largely remained "the responsibility of the business [team]," rather than those working in the compliance department, and that Novartis had not "defined" how that monitoring was to occur or how the business team's findings would be reported to compliance officials. The expert found that there were no written policies or procedures addressing how to conduct investigations of allegations of speaker program abuses and that the reporting of investigative results had not been standardized. The expert also found that Novartis did not consistently undertake "appropriate disciplinary action" for compliance violations in non-termination cases.

3. Novartis shall make the following payments to the United States within fourteen (14) business days of the Effective Date (defined below in Paragraph 35): (i) a payment of $591,442,008.92, plus interest (the "Settlement Amount"), which shall be compounded annually at 2.5% accruing from May 17, 2019, to the date on which the Settlement Amount is paid to the United States; and (ii) a payment of $38,406,717.42 million (the "Forfeiture Amount") as money subject to forfeiture to the United States under 18 U.S.C. § 981(a)(1)(C). Novartis shall pay the Settlement Amount and Forfeiture Amount in accordance with instructions to be provided by the United States Attorney's Office for the Southern District of New York. Of the Settlement Amount, $295,721,004.46, and the interest associated with that amount, constitutes restitution to the United States.

4. Novartis agrees to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Stipulation. Upon reasonable notice, Novartis shall encourage, and agrees not to impair, the cooperation of its directors, officers, and employees, and shall use its best efforts to make available, and encourage, the cooperation of former directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals. Novartis further agrees to furnish to the United States, upon request, complete and unredacted copies of all non-privileged documents, reports, memoranda of

interviews, and records in its possession, custody, or control concerning any investigation of the Covered Conduct that it has undertaken, or that has been performed by another on its behalf.

5. Subject to the exceptions in Paragraphs 11 and 20 below (concerning excluded claims and bankruptcy proceedings), and conditioned upon Novartis's full compliance with the terms of this Stipulation, including full payment of the Settlement Amount and the Forfeiture Amount to the United States pursuant to Paragraph 3 above, the United States releases Novartis, including its subsidiaries and corporate predecessors, successors and assigns, from any civil or administrative monetary claim that the United States has for the Covered Conduct under the FCA, the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a, the Program Fraud Civil Remedies Act, 31 U.S.C. § 3801-3812, and the common law theories of fraud, payment by mistake, and unjust enrichment. For avoidance of doubt, this Stipulation does not release any current or former officer, director, employee, or agent of Novartis from liability of any kind.

6. Subject to the exceptions in Paragraph 11 below (concerning excluded claims), conditioned upon Novartis's full and timely payment of the Forfeiture Amount, and the entry of the Forfeiture Order by the Court, the United States, on behalf of itself, its officers, agencies and departments, releases any claim the United States has under 18 U.S.C. § 981(a)(1) for the Covered Conduct. For avoidance of doubt, this Stipulation does not release any current or former officer, director, employee, or agent of Novartis from liability of any kind.

7. In consideration of the obligations of Novartis in this Stipulation and the Corporate Integrity Agreement ("CIA") entered into between the Office of Inspector General, Department of Health and Human Services ("OIG-HHS") and Novartis's indirect parent company, Novartis Corporation, and conditioned upon Novartis' full payment of the Forfeiture Amount and the Settlement Amount to the United States pursuant to Paragraph 3 above, the OIG-HHS agrees to

release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from Medicare, Medicaid, and other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) against Novartis under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law) or 42 U.S.C. § 1320a-7(b)(7) (permissive exclusion for fraud, kickbacks, and other prohibited activities) for the Covered Conduct, except as reserved in Paragraph 11 (concerning excluded claims), below, and as reserved in this Paragraph. The OIG-HHS expressly reserves all rights to comply with any statutory obligations to exclude Novartis from Medicare, Medicaid, and other Federal health care programs under 42 U.S.C. § 1320a-7(a) (mandatory exclusion) based upon the Covered Conduct. Nothing in this Paragraph precludes the OIG-HHS from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 11, below.

8. Novartis fully and finally releases the United States, and its agencies, officers, employees, servants, and agents from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that Novartis has asserted, could have asserted, or may assert in the future against the United States, and its agencies, officers, employees, servants, and agents, related to the Covered Conduct and the United States' investigation, prosecution and settlement thereof.

9. Conditioned on Novartis's timely payment of the full Settlement Amount pursuant to Paragraph 3 above, Relator, for himself and his heirs, successors, attorneys, agents, and assigns, releases Novartis, including its subsidiaries, predecessors, and corporate successors and assigns, as well as all of its current and former officers, directors, employees, attorneys, and other agents, from any and all manner of claims, proceedings, liens, and causes of action of any kind or description that Relator has against Novartis related to or arising from the Relator's Action;

provided however, that nothing in this Stipulation shall preclude Relator from seeking to recover his reasonable expenses and attorneys' fees and costs pursuant to 31 U.S.C. § 3730(d). Pursuant to 31 U.S.C. § 3730(d)(1), the Government consents to Relator's settlement and dismissal of the Relator Action.

10. In consideration of the execution of this Stipulation by Relator and Relator's release as set forth in Paragraph 9 above, Novartis, including its subsidiaries, predecessors, and corporate successors and assigns, as well as all of its current and former officers, directors, employees, attorneys, and other agents, release Relator, and his heirs, attorneys, agents, successors, and assigns, from any and all manner of claims, proceedings, liens, and causes of action of any kind or description that Novartis has against Relator related to or arising from the Relator's Complaint.

11. Notwithstanding the releases given in Paragraphs 5, 6, 7 and 9 of this Stipulation, or any other term of this Stipulation, the following claims of the Government are specifically reserved and are not released by this Stipulation:

a. Any civil, criminal or administrative claims arising under Title 26, U.S. Code (Internal Revenue Code);

b. Any criminal liability;

c. Except as explicitly stated in this Stipulation, any administrative liability, including but not limited to mandatory exclusion from Federal health care programs under 42 U.S.C. § 1320a-7(a);

d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;

e. Any liability based upon obligations created by this Stipulation; and

f. Any liability of individuals.

12. Novartis shall be in default of this Stipulation if it fails to pay the Settlement Amount and/or the Forfeiture Amount as set forth in Paragraph 3 on or before the due date for

such payments, or if it fails to comply materially with any other term of this Stipulation that applies to it ("Default"). The Government shall provide written notice to Novartis of any Default in the manner set forth in Paragraph 34 below, except for violations of Paragraph 15, which shall be governed by the procedures set forth therein. Novartis shall then have an opportunity to cure the Default within ten (10) calendar days from the date of delivery of the notice of Default. In the event that a Default is not fully cured within ten (10) calendar days of the delivery of the notice of Default ("Uncured Default"), interest shall accrue at the rate of 12% per annum compounded daily on the remaining unpaid principal balance of the Settlement Amount, beginning ten (10) calendar days after mailing of the notice of Default. In the event of an Uncured Default, Novartis shall agree to the entry of a consent judgment in favor of the United States against Novartis in the amount of the Settlement Amount as attached hereto as Exhibit A. The United States may also, at its option, (a) rescind this Stipulation and reinstate the claims asserted against Novartis in the Government Complaint; (b) seek specific performance of this Stipulation; (c) offset the remaining unpaid balance of the Settlement Amount from any amounts due and owing Novartis by any department, agency, or agent of the United States; or (d) exercise any other rights granted by law, or under the terms of this Stipulation, or recognizable at common law or in equity. Novartis shall not contest any offset imposed or any collection undertaken by the Government pursuant to this Paragraph, either administratively or in any Federal or State court. In addition, Novartis shall pay the Government all reasonable costs of collection and enforcement under this Paragraph, including attorneys' fees and expenses. In the event that the United States opts to rescind this Stipulation pursuant to this Paragraph, Novartis shall not plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any civil or administrative claims that relate to the Covered Conduct.

13. The Relator and his heirs, successors, attorneys, agents, and assigns shall not object to this Stipulation; Relator agrees and confirms that the terms of this Stipulation are fair, adequate, and reasonable under all the circumstances, pursuant to 31 U.S.C. § 3730(c)(2)(B).

14. Novartis waives and shall not assert any defenses it may have to any criminal prosecution or federal administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Stipulation bars a remedy sought in such federal criminal prosecution or federal administrative action.

15. Novartis, having truthfully admitted to the conduct set forth in paragraph 2 hereof (the "Admitted Conduct"), agrees it shall not, through its attorneys, agents, officers, or employees, make any public statement, including but not limited to, any statement in a press release, social media forum, or website, that contradicts or is inconsistent with the Admitted Conduct or suggests that the Admitted Conduct is not wrongful (a "Contradictory Statement"). Any Contradictory Statement by Novartis, its attorneys, agents, officers, or employees, shall constitute a violation of this Stipulation, thereby authorizing the Government to pursue any of the remedies set forth in Paragraph 12 above, or seek other appropriate relief from the Court. Before pursuing any remedy, the Government shall notify Novartis that it has determined that Novartis has made a Contradictory Statement. Upon receiving notice from the Government, Novartis may cure the violation by repudiating the Contradictory Statement in a press release or other public statement within four business days. If Novartis learns of a potential Contradictory Statement by its attorneys, agents, officers, or employees, Novartis must notify the Government of the statement within 24 hours. The decision as to whether any statement constitutes a Contradictory Statement or will be imputed

to Novartis for the purpose of this Stipulation, or whether Novartis adequately repudiated a Contradictory Statement to cure a violation of this Stipulation, shall be within the sole discretion of the Government. Consistent with this provision, Novartis may raise defenses and/or assert affirmative claims or defenses in any proceeding brought by private and/or public parties, so long as doing so would not contradict or be inconsistent with the Admitted Conduct.

16. The CIA includes the following requirements, described in Section III.B.2.i of the CIA, which are hereby incorporated into this Stipulation:

a. Novartis may provide remuneration, directly or indirectly, to healthcare professionals ("HCPs") who are not Novartis employees to serve as presenters on behalf of Novartis, including at independent third-party scientific or medical conferences, or participate in speaker training programs (hereafter "Speaker Programs"), only under the circumstances set forth below. Non-Novartis employee HCPs who are engaged by Novartis to present at Speaker Programs shall be referred to collectively herein as "External Speakers" and the activities shall be referred to collectively as "External Speaker Programs."

b. The External Speaker Programs shall be conducted in a virtual format meaning that the External Speakers shall be remote and shall not be in the same location as any audience member. Speaker Programs may not take place in restaurant venues and alcohol may not be served or available for purchase at such events.

c. The External Speaker Programs may occur only within 18 months of the FDA approval of any new Novartis products that are: (i) marketed or sold

by Novartis in the United States (or pursuant to contracts with the United States), and (ii) reimbursed by Federal health care programs ("Government Reimbursed Products"), or a new indication for any Government Reimbursed Product previously approved by the FDA. Such programs may include the opportunity for the real-time discussion of questions and answers between the External Speaker and any audience member. Novartis may record External Speaker Programs (including the question and answer exchanges) and make such recordings available during and following the expiration of the 18-month period referenced above.

d. For each newly approved Government Reimbursed Product or new indication for a Government Reimbursed Product, Novartis may provide no more than a maximum of $100,000 in total remuneration (whether direct or indirect) to all External Speakers for External Speaker Programs for such product or indication, and each External Speaker shall receive no more than a maximum of $10,000 in total remuneration associated with serving as an External Speaker for such product or indication. The above-referenced monetary limits shall include remuneration for speaking and for speaker training, but shall not include any direct payment by Novartis for travel and travel-related expenses (e.g., hotels, rental cars, etc.)

17. On the due date for the submission of each Annual Report required under the CIA, an officer, director, or senior management employee of Novartis (the "Certifying Official") shall submit a certification to HHS-OIG covering the applicable CIA Reporting Period, attesting that to the best of his or her knowledge, Novartis has complied with the requirements set forth in

Paragraph 16, or if there has been any failure to comply with the terms of Paragraph 16 during a given year, the certification shall include a description of any and all such instances of non-compliance and the corrective action taken to address such non-compliance.

18. If HHS-OIG determines that Novartis or the Certifying Official has failed to comply with the requirements referenced in Paragraphs 16 and 17 above, then, in addition to imposing any applicable remedies available under Section X of the CIA, HHS-OIG may, in its sole discretion, refer such alleged violation to the United States Attorney's Office for the Southern District of New York for purposes of seeking relief from the Court in the form of (1) injunctive relief with respect to Novartis' execution of External Speaker Programs, as defined in Paragraph 16, for the remaining term of the CIA; or (2) monetary penalties against the Certifying Official. Only after receiving a referral from HHS-OIG may the United States seek relief from the Court for any violation of Paragraphs 16 and 17 above. Prior to making any referral to the United States Attorney's Office, (i) HHS-OIG shall provide written notice to Novartis and/or the Certifying Official of the alleged violation of Paragraphs 16 or 17, and (ii) Novartis and/or the Certifying Official shall have 30 days from the date of receipt of the written notice to respond to HHS-OIG's written notice. In any proceeding seeking relief pursuant to this Paragraph, the Government will have the burden of demonstrating to the Court that Novartis or the Certifying Official is in substantial noncompliance with the terms of Paragraphs 16 and/or 17.

19. Novartis represents and warrants that it has reviewed its financial situation, that it is currently not insolvent as such term is defined in 11 U.S.C. § 101(32) and that it reasonably believes that it shall remain solvent following payment to the Government of the Settlement Amount and the Forfeiture Amount. Further, the Settling Parties warrant that, in evaluating whether to execute this Stipulation, they (a) have intended that the mutual promises, covenants,

and obligations set forth constitute a contemporaneous exchange for new value given to Novartis, within the meaning of 11 U.S.C. § 547(c)(1); and (b) have concluded that these mutual promises, covenants, and obligations do, in fact, constitute such a contemporaneous exchange. Further, the Settling Parties warrant that the mutual promises, covenants, and obligations set forth herein are intended to and do, in fact, represent a reasonably equivalent exchange of value that is not intended to hinder, delay, or defraud any entity to which Novartis was or became indebted to on or after the date of this Stipulation, within the meaning of 11 U.S.C. § 548(a)(1).

20. If within 91 days of the Effective Date of this Stipulation or any payment made under this Stipulation, Novartis commences any case, action, or other proceeding under any law relating to bankruptcy, insolvency, reorganization, or relief of debtors or a third party commences any case, action, or other proceeding under any law related to bankruptcy, insolvency, reorganization, or relief of debtors (a) seeking an order for relief of Novartis's debts, or seeking to adjudicate Novartis as bankrupt or insolvent; or (b) seeking appointment of a receiver, trustee, custodian, or other similar official for Novartis or for all or part of Novartis's assets, Novartis agrees as follows:

a. Novartis's obligations under this Stipulation may not be avoided pursuant to 11 U.S.C. § 547, and Novartis shall not argue or otherwise take the position in any such case, action, or proceeding that (i) Novartis's obligations under this Stipulation may be avoided under 11 U.S.C. § 547; (ii) Novartis was insolvent at the time this Stipulation was entered into; or (iii) the mutual promises, covenants, and obligations set forth in this Stipulation do not constitute a contemporaneous exchange for new value given to Novartis.

b. If any of Novartis's obligations under this Stipulation are avoided for any

reason, including, but not limited to, through the exercise of a trustee's avoidance powers under the Bankruptcy Code, the Government, at its option, may rescind the release in this Stipulation and bring any civil and/or administrative claim, action, or proceeding against Novartis for the claims that would otherwise be covered by the releases in Paragraph 5, 6 and 7 above. Novartis agrees that (i) any such claim, action, or proceeding brought by the Government would not be subject to an "automatic stay" pursuant to 11 U.S.C. § 362(a) as a result of the case, action, or proceeding described in the first sentence of this Paragraph, and Novartis shall not argue or otherwise contend that the Government's claim, action, or proceeding is subject to an automatic stay; (ii) Novartis shall not plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any claim, action, or proceeding that is brought by the Government within 60 calendar days of written notification to Novartis that the releases have been rescinded pursuant to this Paragraph, except to the extent such defenses were available on January 5, 2011, and (iii) the Government has a valid claim against Novartis in the combined amount of the Settlement Amount and the Forfeiture Amount and the Government may pursue its claim in the case, action, or proceeding described in the first sentence of this Paragraph, as well as in any other case, action, or proceeding.

c. Novartis acknowledges that the agreements in this Paragraph are provided in exchange for valuable consideration provided in this Stipulation.

21. Novartis agrees as follows:

a. Novartis agrees that the Forfeiture Amount represents a substitute *res* for net proceeds obtained by Novartis as a result of the Admitted Conduct , and that the Forfeiture Amount is subject to civil forfeiture to the United States pursuant to 18 U.S.C. § 981(a)(1)(C). Novartis further agrees that this Stipulation may be attached and incorporated into a civil forfeiture complaint (the "Civil Forfeiture Complaint") that will be filed against the Forfeiture Amount in the United States District Court for the Southern District of New York. Novartis releases any and all claims it may have to such funds.

b. Novartis expressly consents to the forfeiture of the Forfeiture Amount to the United States and waives any challenge to the Civil Forfeiture Complaint, including but not limited to all constitutional and statutory challenges to any forfeiture carried out in accordance with this Agreement on any grounds, including that the forfeiture constitutes an excessive fine or punishment. Novartis also waives service of the Civil Forfeiture Complaint and consents to *in rem* jurisdiction as to the Forfeiture Amount.

c. Upon approval of this Stipulation, Novartis shall release any and all claims it may have to the Forfeiture Amount and execute such documents necessary to accomplish forfeiture of the funds. Novartis agrees that it will not file a claim with any Court or otherwise contest the civil forfeiture of the Forfeiture Amount and will not assist a third party in asserting any claim to the Forfeiture Amount. Novartis certifies that the funds used to pay the Forfeiture Amount are not the subject of any lien, security agreement, or other encumbrance. Transferring encumbered funds or failing to pass clean title to these funds in any way will be considered a breach of this Stipulation.

d. Novartis agrees that the Forfeiture Amount shall be treated as a penalty paid to the United States government for tax purposes. Novartis agrees that it will not claim, assert, or apply for a tax deduction or tax credit with regard to any federal, state, local or foreign tax for the Forfeiture Amount.

22. Novartis agrees to the following:

a. Unallowable Costs Defined: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk-1 and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Novartis, including its present or former officers, directors, employees, and agents in connection with:

1. the matters covered by this Stipulation;
2. the United States' audit(s) and civil investigation(s) of matters covered by this Stipulation;
3. Novartis's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil investigation(s) in connection with matters covered by this Stipulation (including attorneys' fees);
4. the negotiation and performance of this Stipulation;
5. any payment Novartis makes to the United States pursuant to this Stipulation and any payment Novartis may make to Relator, including expenses, costs and attorneys' fees; and
6. the negotiation of the CIA, and obligations undertaken pursuant to the CIA to: (i) retain an independent review organization to perform annual reviews as described in Section III of the CIA; and (ii) prepare and submit reports to the OIG-HHS

are unallowable costs for government contracting purposes and under the Medicare Program, Medicaid Program, TRICARE Program, and Federal

Employees Health Benefits Program (FEHBP) (hereinafter referred to as "Unallowable Costs"). However, nothing in Paragraph 22.a.6 that may apply to the obligations undertaken pursuant to the CIA affects the status of costs that are not allowable based on any other authority applicable to Novartis.

b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by Novartis, and Novartis shall not charge such Unallowable Costs directly or indirectly to any contracts with the United States.

c. Treatment of Unallowable Costs Previously Submitted for Payment: Within 90 days of the Effective Date of this Stipulation, Novartis shall identify and repay by adjustment to future claims for payment or otherwise any Unallowable Costs (as defined in this Paragraph) included in payments previously sought by Novartis from the United States. Novartis agrees that the United States, at a minimum, shall be entitled to recoup from Novartis any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted requests for payment. Any payments due shall be paid to the United States pursuant to the direction of the Department of Justice and/or the affected agencies. The United States, including the Department of Justice and/or the affected agencies, reserves its right to audit, examine, or re-examine Novartis's books and records and to disagree with any calculation submitted by Novartis or any of its subsidiaries or affiliates regarding any Unallowable Costs included in payments previously sought by Novartis, or the effect of any such Unallowable Costs on the amounts of such payments.

d. Nothing in this Stipulation shall constitute a waiver of the rights of the United States to audit, examine, or re-examine Novartis's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

23. This Stipulation is intended to be for the benefit of the Settling Parties only. The Settling Parties do not release any claims against any other person or entity except as otherwise provided herein.

24. Each of the Settling Parties shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Stipulation; provided, however, that nothing in this Stipulation shall preclude Relator from seeking to recover his expenses or attorneys' fees and costs from Novartis, pursuant to 31 U.S.C. § 3730(d) and analogous provisions in state law.

25. Any failure by the United States to insist upon the full or material performance of any of the provisions of this Stipulation shall not be deemed a waiver of any of the provisions hereof, and the United States, notwithstanding that failure, shall have the right thereafter to insist upon the full or material performance of any and all of the provisions of this Stipulation.

26. This Stipulation is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Stipulation is the United States District Court for the Southern District of New York. The Court will retain jurisdiction over the enforcement and interpretation of this Stipulation and to resolve all disputes arising hereunder.

27. For purposes of construing this Stipulation, it shall be deemed to have been drafted by the Settling Parties, and shall not, therefore, be construed against any Settling Party for that reason in any subsequent dispute.

28. This Stipulation constitutes the entire agreement between the Settling Parties with respect to the subject matter thereof. This Stipulation may not be amended except by written consent of the Settling Parties. No prior agreements, oral representations or statements shall be considered part of this Stipulation.

29. The undersigned counsel and other signatories represent and warrant that they are fully authorized to enter into this Stipulation on behalf of the persons and the entities indicated below.

30. This Stipulation is binding on Novartis's successor entities.

31. This Stipulation is binding on Relator's successors, transferees, heirs, and assigns.

32. This Stipulation may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Stipulation. E-mails that attach signatures in PDF form or facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Stipulation.

33. Novartis agrees that it waives and shall not seek payment of any of the health care billings covered by this Stipulation from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third-party payors based upon the claims defined as the Covered Conduct.

34. Any notice pursuant to this Stipulation shall be in writing and shall, unless expressly provided otherwise herein, be delivered by hand, express courier, or e-mail transmission followed by postage-prepaid mail, and shall be addressed as follows:

TO THE UNITED STATES:

Jeannette A. Vargas
Pierre G. Armand
Mónica Folch
Jacob T. Lillywhite

Jennifer A. Jude
Jacob M. Bergman
Assistant United States Attorneys
United States Attorney's Office
Southern District of New York
86 Chambers Street, Third Floor
New York, New York 10007
Email: Jeannette.Vargas@usdoj.gov
Pierre.Armand@usdoj.gov
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Jacob.Lillywhite@usdoj.gov
Jennifer.Jude@usdoj.gov
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TO NOVARTIS:

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Rachel G. Skaistis, Esq.
Benjamin Gruenstein, Esq.
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New York, New York 10019
Email: echesler@cravath.com
rskaistis@cravath.com
bgruenstein@cravath.com

TO THE RELATOR:

James E. Miller
Laurie Rubinow
Shepherd Finkelman Miller & Shah, LLP
65 Main Street
Chester, CT 06412
Email: jmiller@sfmslaw.com
lrubinow@sfmslaw.com

35. The effective date of this Stipulation is the date upon which this Stipulation is entered by the Court (the "Effective Date").

For Novartis Pharmaceuticals Corp.:

Dated: June 29, 2020

CRAVATH, SWAINE, & MOORE LLP

By: _____
EVAN R. CHESLER, Esq.
RACHEL G. SKAISTIS, Esq.
BENJAMIN GRUENSTEIN, Esq.
Worldwide Plaza
825 Eighth Avenue
New York, New York 10019

NOVARTIS PHARAMCEUTICALS CORPORATION

By: _____
ELIZABETH MCGEE
General Counsel, US Pharma
US Country Head Legal
Novartis Pharmaceuticals Corporation

For the United States of America:

Dated: June 29, 2020

AUDREY STRAUSS
Acting United States Attorney

By: _____
JEANNETTE A. VARGAS
MÓNICA FOLCH
JACOB T. LILLYWHITE
PIERRE G. ARMAND
JENNIFER A. JUDE
JACOB M. BERGMAN
Assistant United States Attorneys
86 Chambers Street, Third Floor
New York, NY 10007

For Relator Oswald Billota:

Dated: June 29, 2020

SHEPHERD FINKELMAN MILLER & SHAH, LLP

By: DocuSigned by: James Miller 6D8DBB42154C489...
JAMES E. MILLER, Esq.
65 Main Street
Chester, CT 06412

DocuSigned by: Oswald Bilotta F21608F352964FC...
OSWALD BILOTTA

For OIG-HHS:

Dated: June 29, 2020

By: _____
LISA M. RE
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of
Health and Human Services

For Novartis Pharmaceuticals Corp.:

Dated: June 29, 2020

CRAVATH, SWAINE, & MOORE LLP

By: _____
EVAN R. CHESLER, Esq.
RACHEL G. SKAISTIS, Esq.
BENJAMIN GRUENSTEIN, Esq.
Worldwide Plaza
825 Eighth Avenue
New York, New York 10019

NOVARTIS PHARAMCEUTICALS CORPORATION

By: _____
ELIZABETH MCGEE
General Counsel, US Pharma
US Country Head Legal
Novartis Pharmaceuticals Corporation

For the United States of America:

Dated: June 29, 2020

AUDREY STRAUSS
Acting United States Attorney

By: _____
JEANNETTE A. VARGAS
MÓNICA FOLCH
JACOB T. LILLYWHITE
PIERRE G. ARMAND
JENNIFER A. JUDE
JACOB M. BERGMAN
Assistant United States Attorneys
86 Chambers Street, Third Floor
New York, NY 10007

For Relator Oswald Billota:

Dated: June 29, 2020

SHEPHERD FINKELMAN MILLER & SHAH, LLP

By: _____
JAMES E. MILLER, Esq.
65 Main Street
Chester, CT 06412

_____
OSWALD BILOTTA

For OIG-HHS:

Dated: June 29, 2020

GREGORY DEMSKE
Digitally signed by GREGORY DEMSKE
Date: 2020.06.30 15:24:17 -04'00'

By: _____
LISA M. RE
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Services

For Novartis Pharmaceuticals Corp.:

Dated: June 29, 2020

CRAVATH, SWAINE, & MOORE LLP

By: _____
EVAN R. CHESLER, Esq.
RACHEL G. SKAISTIS, Esq.
BENJAMIN GRUENSTEIN, Esq.
Worldwide Plaza
825 Eighth Avenue
New York, New York 10019

NOVARTIS PHARAMCEUTICALS CORPORATION

By: _____
ELIZABETH MCGEE
General Counsel, US Pharma
US Country Head Legal
Novartis Pharmaceuticals Corporation

For the United States of America:

Dated: June 29, 2020

AUDREY STRAUSS
Acting United States Attorney

By: _____
JEANNETTE A. VARGAS
MÓNICA FOLCH
JACOB T. LILLYWHITE
PIERRE G. ARMAND
JENNIFER A. JUDE
JACOB M. BERGMAN
Assistant United States Attorneys
86 Chambers Street, Third Floor
New York, NY 10007

For Relator Oswald Billota:

Dated: June 29, 2020

SHEPHERD FINKELMAN MILLER & SHAH, LLP

By: _____
JAMES E. MILLER, Esq.
65 Main Street
Chester, CT 06412

_____
OSWALD BILOTTA

For OIG-HHS:

Dated: June 29, 2020

By: _____
LISA M. RE
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of
Health and Human Services

Jacob.Bergman@usdoj.gov

TO NOVARTIS:

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rskaistis@cravath.com
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TO THE RELATOR:

James E. Miller
Laurie Rubinow
Shepherd Finkelman Miller & Shah, LLP
65 Main Street
Chester, CT 06412
Email: jmiller@sfmslaw.com
lrubinow@sfmslaw.com

35. The effective date of this Stipulation is the date upon which this Stipulation is entered by the Court (the "Effective Date").

For Novartis Pharmaceuticals Corp.:

Dated: June 29, 2020

CRAVATH, SWAINE, & MOORE LLP

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Dated: June 29, 2020

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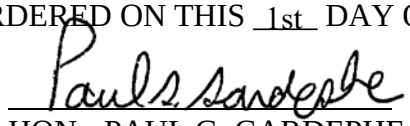
SO ORDERED ON THIS 1st DAY OF July, 2020:



HON. PAUL G. GARDEPHE
UNITED STATES DISTRICT COURT JUDGE